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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,855	10/31/2003	Jens Holm	04305/100M237-US1	9333
7278	7590	08/25/2004	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			TSAY, MARSHA M	
			ART UNIT	PAPER NUMBER

1653

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,855

Applicant(s)

HOLM ET AL.

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-75 are currently pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, 19-20, 21-32, 52-57, 59, 73, drawn to a scaffold protein variant where the naturally occurring allergen is a pollen allergen, classified in class 514, subclass 12.
 - II. Claims 1-17, 19-20, 33, 52-57, 59, 73, drawn to a scaffold protein variant where the naturally occurring allergen originates from *Poales*, classified in class 514, subclass 12.
 - III. Claims 1-17, 19-20, 34, 52-57, 59, 73, drawn to a scaffold protein variant where the naturally occurring allergen originates from *Asterales* or *Urticales*, classified in class 514, subclass 12.
 - IV. Claims 1-17, 19-20, 35-43, 52-57, 59, 73, drawn to a scaffold protein variant where the naturally occurring allergen is a dust mite allergen, classified in class 514, subclass 12.
 - V. Claim 1-17, 19-20, 44, 52-57, 59, 73, drawn to a scaffold protein variant where the naturally occurring allergen is a cockroach allergen, classified in class 514, subclass 12.
 - VI. Claims 1-17, 19-20, 45-46, 52-57, 59, 73, drawn to a scaffold protein variant where the naturally occurring allergen is a mammalian allergen, classified in class 514, subclass 12.

- VII. Claims 1-17, 19-20, 47-50, 52-57, 59, 73, drawn to a scaffold protein variant where the naturally occurring allergen is a venom allergen, classified in class 514, subclass 12.
- VIII. Claims 1-17, 19-20, 51, 52-57, 59, 73, drawn to a scaffold protein variant where the naturally occurring allergen is a food allergen, classified in class 514, subclass 12.
- IX. Claim 18, drawn to a method of producing a recombinant protein variant with ability to induce a protective immune response, classified in class 435, subclass 69.1.
- X. Claim 58, drawn to a method of treating allergy, classified in class 424, subclass 1.11. or class 514, subclass 12.
- XI. Claims 60, 61, drawn to a method of generating an immune response, classified in class 514, subclass 12.
- XII. Claims 62, 63, drawn to a method of vaccination, classified in class 514, subclass 12.
- XIII. Claims 64, 65, drawn to a method of treating allergic reactions, classified in class 514, subclass 12.
- XIV. Claim 66, drawn to a method of preparing a recombinant protein variant, classified in class 435, subclass 69.1.
- XV. Claims 67-72, drawn to DNA encoding a recombinant protein, classified in class 536, subclass 23.1.

XVI. Claims 74, 75, drawn to a diagnostic assay, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are scaffold protein variants which are different in sequence and structure as indicated by the introduction of primary mutations to their amino acid sequence, as well as to the different naturally occurring allergen that each is drawn to.

Inventions IX, XIV and I-VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the synthetic steps of either Inventions IX, XIV can be used to make (any of) the scaffold proteins (of Inventions I-VIII).

Inventions I-VIII and X-XIII, XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the scaffold protein from any one of Inventions I-VIII can be used for any of the methods of Inventions X-XIII, XVI.

Inventions I-VIII and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are the scaffold protein variants of Inventions I-VIII and DNA of Invention XV.

Inventions XV and IX-XIV, XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention XV cannot be used in any of the methods of Inventions IX-XIV, XVI.

Inventions IX, XIV and X-XIII, XVI are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Inventions IX and XIV are both methods of making scaffold protein variants. However, the steps that are used to make the product are different and therefore Inventions IX and XIV are patentably distinct.

Inventions X-XIII, XVI are methods of using the protein variants. However, any of the methods of Inventions X-XIII, XVI is directed towards a different use and outcome, therefore making Inventions X-XIII, XVI patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

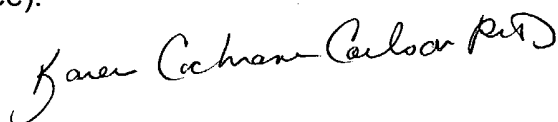
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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Karen Cochrane Carlson" followed by a stylized "P.D." or similar initials.

MT
August 9, 2004

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER